

# **Electronic Drug Establishment Registration & Drug Listing in SPL Format**

**HL7 SPL WG Process Team Meeting  
October 15, 2008**

Lonnie Smith  
Project Manager  
FDA Data Standards Council



# Registration of Manufacturing Facilities

- Each Registrant (owner/operator firm) must submit one SPL file with registration information for all of its facilities (unlimited amount of domestic or foreign establishments per file)
- Updates of information require re-submission of the same updated SPL file (i.e., same setID; at least annually)
- Simplified SPL files are submitted for 'No Change' or 'Out of Business' notification

# Establishment Registration SPL

- **Document Information**

- Type of Document
- ID
- Set ID
- Version Number
- Effective Time

- **Registrant**

- Name
- DUNS Number

- **Registrant Contact**

- Name
- Mailing Address
- City
- State
- Country
- Postal Code
- Telephone Number
- Email Address

# Establishment Registration SPL (cont...)

- **Establishment**
  - Name
  - DUNS Number
  - FEI
  - Street Address
  - City
  - State
  - Country
  - Postal Code
  - Type of Operation(s)
- **Establishment Contact**
  - Name
  - Mailing Address
  - City
  - State
  - Country
  - Postal Code
  - Telephone Number
  - Email Address

# Establishment Information for Inactive Ingredient Manufacturers

- Establishment information for manufacturers of **inactive ingredients** in your products to be listed – does **NOT** need to be included in your electronic drug listing SPL.


# Establishment Information for Active Pharmaceutical Ingredient Manufacturers

- Establishment information for manufacturers of your active pharmaceutical ingredient used in your products – Recommendation that this information **should** be included in your electronic drug listing document (SPL file)

# Source NDC Product Code

- “The Source NDC Product Code is used when a marketed drug product is repacked or relabeled.” – SPL Xforms instruction document (section 4.6.8)

# Source NDC Product Code cont...

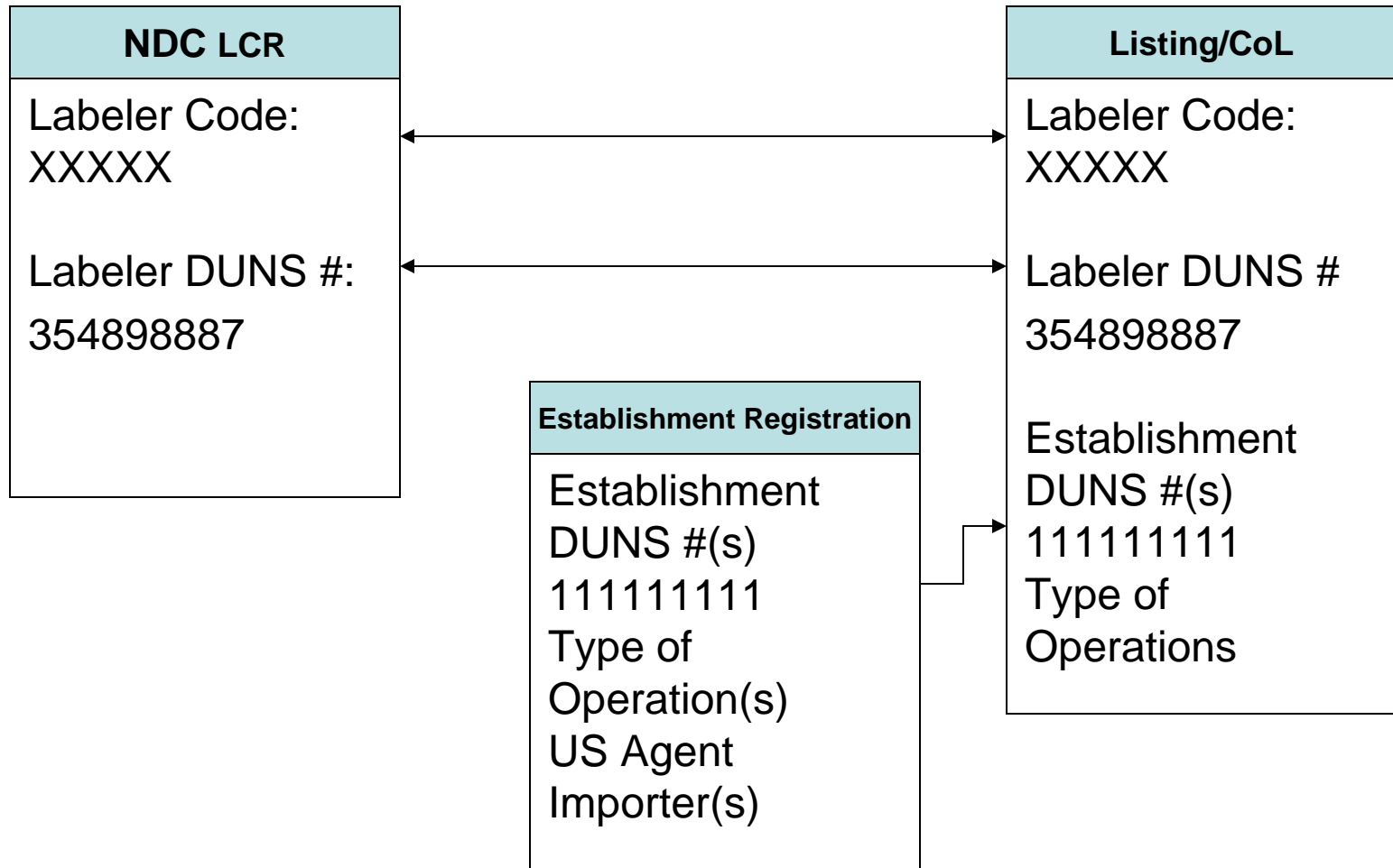
Part 2 of 2		
STERILE WATER water injection		Source NDC Product Code
		
Product Information		
NDC Product Code (Source)	77777-777 (77777-777)	
Route of Administration	INTRAVENOUS	DEA Schedule
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
No Active Ingredients Found		
Inactive Ingredients		
Ingredient Name	Strength	
water	5 mL in 5 mL	
Product Characteristics		



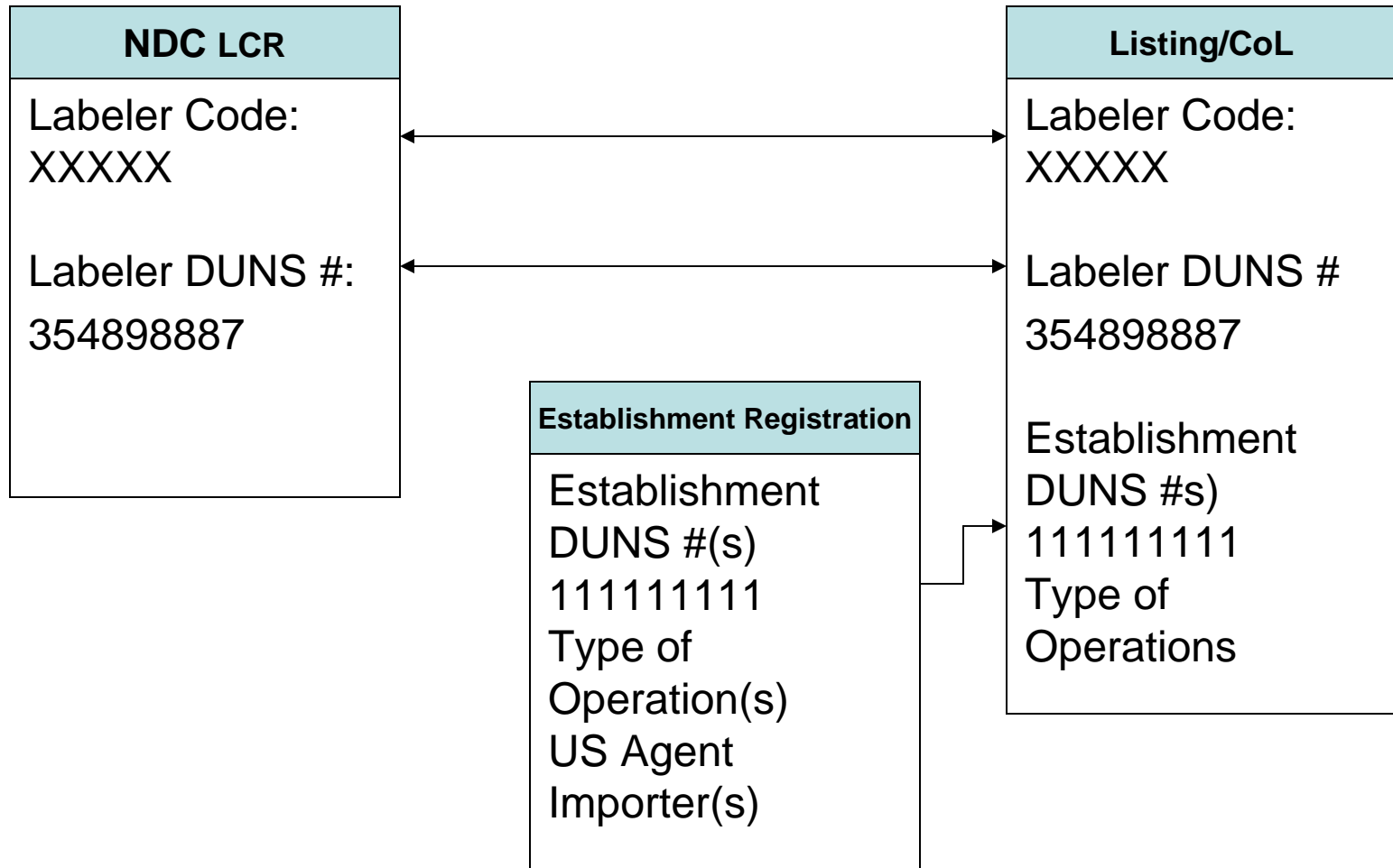
# Order of Submissions

1. NDC Labeler Request (LCR) and Establishment Registration (ER) SPL
  2. CoL/Listing SPL
- CoL/Listing validates against data submitted in NDC LCR and ER SPL

# Data Source – SPL Documents

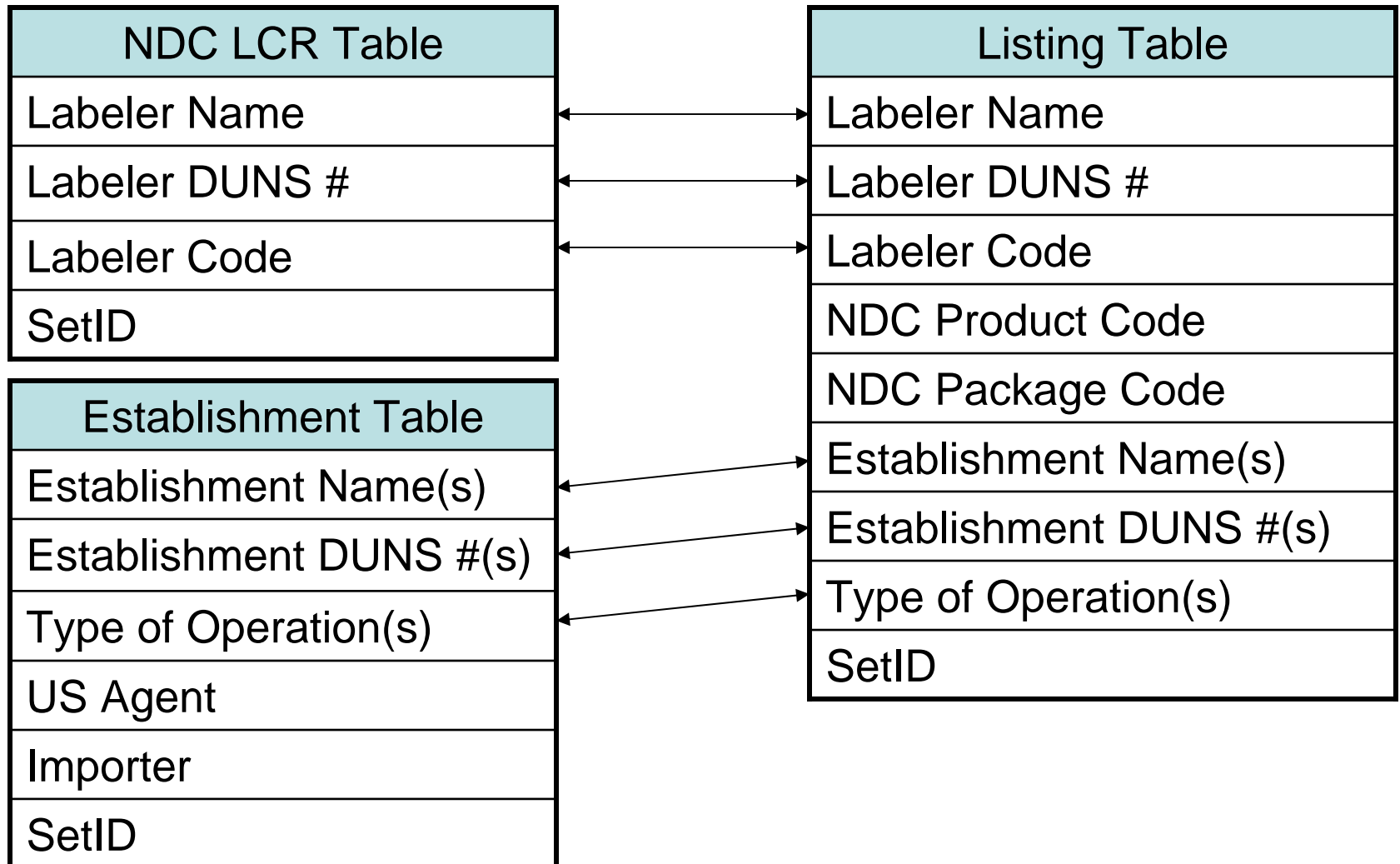


# Data Source – SPL Documents

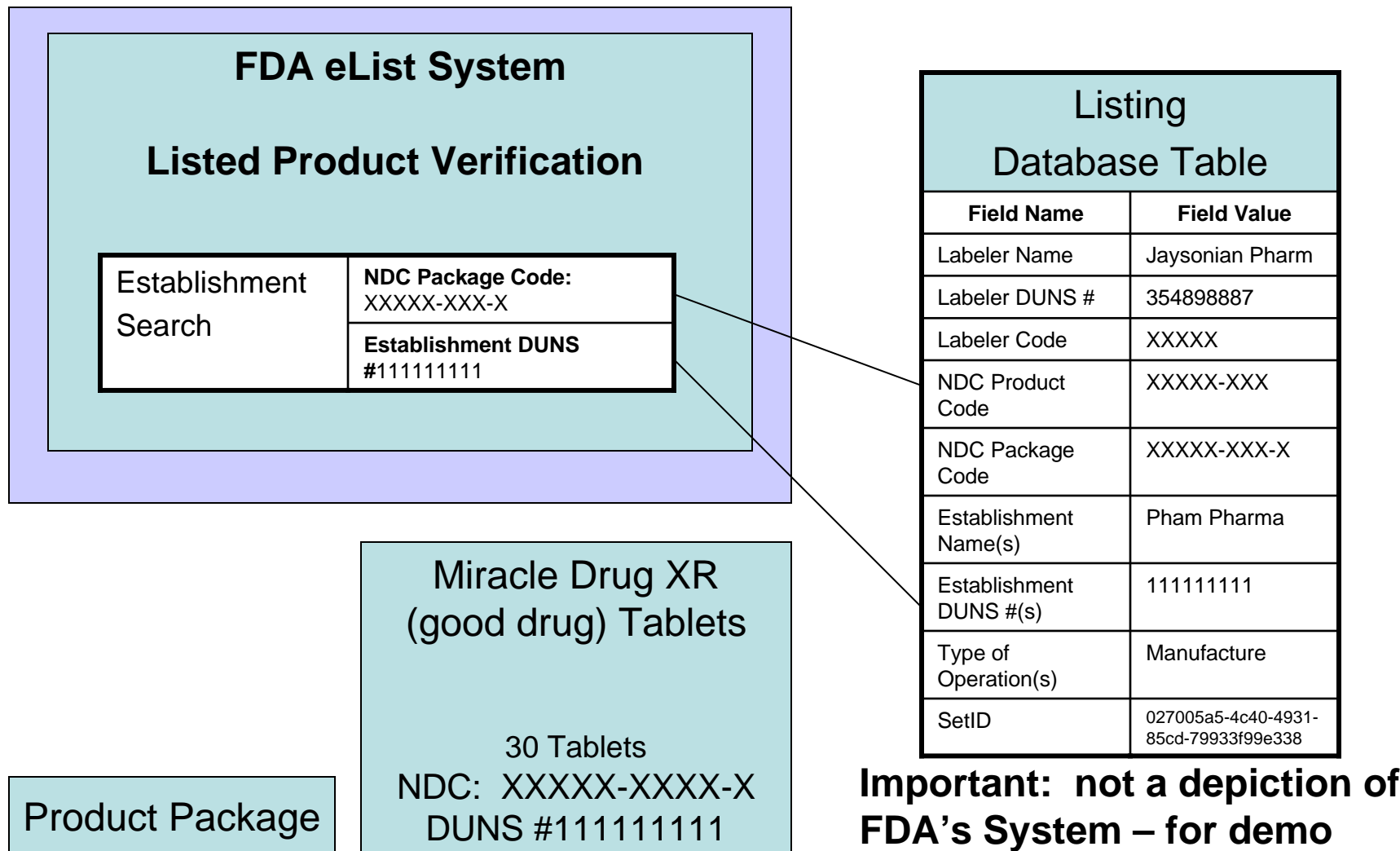


# eList Data Relationships

## Mockup



# Query Example Mockup



# Establishment Registration

## SPL Xforms

### HL7 SPL - Establishment Registration v 0.71

Open Save As Save

Establishment Registration Preview

#### Document Information

Type of Document	ESTABLISHMENT REGISTRATION
ID	4ff69f20-6dc3-49ca-bb3c-0d589ff4c0b1
Set ID	118ec196-50d7-49b2-946a-831d29702818
Version Number	1
Effective Time	20080909

example(YYYYMMDD)

#### Registrant

Name	Acme, Inc.
DUNS Number	2223334441

#### Registrant Contact

Name	Deborah Tyler
Mailing Address	222 Bonifant Avenue
City	Fort Washington
State	PA
Country	USA
Postal Code	35295
Telephone Number	tel:+1-800-435-4585
Email Address	mailto:deborah.tyler@acme.com

example(tel:+1-201-555-1212)  
example(mailto:xportal@globalsubmit.com)

# Establishment Registration

## SPL Xforms cont...

<b>Establishment</b>		
Name	Acme Manufacturing, Inc.	
DUNS Number	475859252	
FEI	35295835928	
<input type="button" value="Add FEI"/> <input type="button" value="Delete FEI"/>		
Street Address	777 Sampson Street	
City	Mason	
State	PA	
Country	USA	
Postal Code	35859	
Type of Operation	manufacture ▼	
<input type="button" value="Add Type of Operation"/> <input type="button" value="Delete Type of Operation"/>		
<b>Establishment Contact</b>		
Name	Pam Jamison	
Mailing Address	777 Sampson Street	
City	Mason	
State	PA	
Country	USA	
Postal Code	35859	
Telephone Number	tel:+1-800-778-8359	example(tel:+1-201-555-1212)
Email Address	mailto:pam.jamison@acme.com	example(mailto:xportal@globalsubmit.com)
<input type="button" value="Add US Agent"/> <input type="button" value="Delete US Agent"/>		
<input type="button" value="Add Importer"/> <input type="button" value="Delete Importer"/>		

# Establishment Registration

## SPL Xforms cont...

Establishment	
Name	Acme International
DUNS Number	98583572
FEI	25835925829
<input type="button" value="Add FEI"/> <input type="button" value="Delete FEI"/>	
Street Address	33 Bleu Rue
City	Paris
State	
Country	FRA
Postal Code	20583
Type of Operation	manufacture
Type of Operation	analysis
<input type="button" value="Add Type of Operation"/> <input type="button" value="Delete Type of Operation"/>	
Establishment Contact	
Name	Etienne St. Champs
Mailing Address	33 Bleu Rue
City	Paris
State	
Country	FRA
Postal Code	20583
Telephone Number	tel:+33-538-5859
Email Address	mailto:etienne.st-champs@acme.com

example(tel:+1-201-555-1212)  
example(mailto:xportal@globalsubmit.com)



# Establishment Registration

## SPL Xforms cont...

<b>Establishment Contact</b>		
Name	Etienne St. Champs	
Mailing Address	33 Bleu Rue	
City	Paris	
State		
Country	FRA	
Postal Code	20583	
Telephone Number	tel:+33-538-5859	example(tel:+1-201-555-1212)
Email Address	mailto:etienne.st-champs@acme.com	example(mailto:xportal@globalsubmit.com)
<b>US Agent</b>		
Name	Acme USA	
DUNS number	359582424	
Telephone Number	tel:+1-800-999-5542	example(tel:+1-201-555-1212)
Email Address	mailto:jacob.goodman@acme.com	example(mailto:xportal@globalsubmit.com)
<input type="button" value="Add US Agent"/> <input type="button" value="Delete US Agent"/>		
<b>Importer</b>		
Name	Franklin Imports	
DUNS number	252597793	
Telephone Number	tel:+1-888-444-5835	example(tel:+1-201-555-1212)
Email Address	mailto:paula.johansen@franklin.com	example(mailto:xportal@globalsubmit.com)
<input type="button" value="Add Importer"/> <input type="button" value="Delete Importer"/>		
<input type="button" value="Add Establishment"/> <input type="button" value="Delete Establishment"/>		

# Establishment Registration SPL Document

Product Information	
Product Type	ESTABLISHMENT REGISTRATION

Registrant - Acme, Inc. (2223334441)			
Contact	Address	Telephone Number	Email Address
Deborah Tyler	Address: 222 Bonifant Avenue City, State, Zip: Fort Washington, PA, 35295 Country: USA	+1-800-435-4585	deborah.tyler@acme.com

Establishment			
Name	Address	ID/FEI	Operations
Acme Manufacturing, Inc.	Address: 777 Sampson Street City, State, Zip: Mason, PA, 35859 Country: USA	475859252	manufacture
Contact	Address	Telephone Number	Email Address
Pam Jamison	Address: 777 Sampson Street City, State, Zip: Mason, PA, 35859 Country: USA	+1-800-778-8359	pam.jamison@acme.com

# Establishment Registration

## SPL Document cont...

	Country: FRA		
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Establishment			
Name	Address	ID/FEI	Operations
Acme International	Address: 33 Bleu Rue City, State, Zip: Paris, 20583 Country: FRA	98583572	manufacture, analysis
Contact	Address	Telephone Number	Email Address
Etienne St. Champs	Address: 33 Bleu Rue City, State, Zip: Paris, 20583 Country: FRA	+33-538-5859	etienne.st-champs@acme.com
US Agent (ID)	Address	Telephone Number	Email Address
Acme USA (359582424)		+1-800-999-5542	jacob.goodman@acme.com
Importer (ID)	Address	Telephone Number	Email Address
Franklin Imports (252597793)		+1-888-444-5835	paula.johansen@franklin.com

Revised: 09/2008

# Establishment Re-Registration

## No Changes

<b>Product Information</b>	
<b>Product Type</b>	NO CHANGE NOTIFICATION

Revised: 04/2008

# Establishment Out of Business Notification

<b>Product Information</b>	
<b>Product Type</b>	OUT OF BUSINESS NOTIFICATION

Revised: 09/2008

# Stay Informed

- FDA Data Standards Council website listserv
  - 21,410 listserv subscribers as of October 2008
  - <http://www.fda.gov/oc/datacouncil/>



# Future SPL R4 Training/Meetings

- October 28, 2008 – Generic Pharmaceutical Association
- October 29 – 30, 2008 – Drug Information Association
- November 17, 2008 - SPL Content of Labeling and Electronic Drug Establishment Registration and Drug Listing for the Biologics Industry; Public Workshop -

# SPL-related Technical Assistance/Questions

- 1:1 Electronic Drug Establishment Registration and Drug Listing Sessions Available
- SPL Release Three and Release Four questions
- SPL e-mail account ([spl@fda.hhs.gov](mailto:spl@fda.hhs.gov))



**Thank you!**